

III. REMARKS

The undersigned gratefully acknowledges the courtesies extended by Examiners Mitchell and Padmanabhan during the telephone interview conducted on January 12, 2004.

A. Status of the Claims

Claims 6-10, 13-16 and 20-24 are pending. Claims 6 and 13 have been amended without prejudice. New claim 24 has been added. Support for the amendments can be found e.g., at page 22, lines 3-8 of the original specification as filed. Applicants respectfully submit that no new matter has been added by virtue of this amendment.

B. Statement of Substance of Interview

During the Interview of January 12, 2004, all of the pending claims and the Paradissis reference were discussed.

It was discussed during the interview that the present claims are directed to methods of treatment with controlled release matrix dosage forms as opposed to the Paradissis reference which is directed to controlled release formulations utilizing a controlled release coating.

In response, the Examiner stated during the interview that the claimed formulations are made by a different process, but are the same as the Paradissis formulations since the reference describes drug mixed with excipient.

In response to the Examiner's statement, it was explained to the Examiner that the Paradissis formulations are prepared by mixing drug with excipient to form an immediate release core which is then overcoated with a controlled release coating, in contrast to the present claims wherein the opioid is incorporated into (i.e., dispersed in) a controlled release matrix which can provide controlled release without the necessity of a controlled release coating.

The Examiner then stated that claim 6 is not novel over Paradissis as the present claims recite "comprising" terminology and therefore can include a controlled release coating, thus encompassing the Paradissis formulations. In response, it was explained to the Examiner that the present claims cannot read on the Paradissis formulations as the reference does not teach

controlled release matrix formulations, but rather, describes immediate release cores coated with a controlled release coating. Therefore, regardless of the “comprising” terminology, the Paradissis reference does not teach or suggest the present claims.

During the interview it was also proposed to amend the claims to recite “incorporated into” rather than “contained in” without prejudice, in order to address the Examiner’s rejections based on this claim terminology.

During the interview, the Examiner also raised the issue that the claims are method of treatment claims, but include a preparation step. In response, it was explained that such a claim is proper as the claims do recite an administration step. However, in order to advance the prosecution of the application, the preparation step has been deleted without prejudice.

B. Rejection of Claims 6-7, 9 and 13-16 under 35 U.S.C. § 102(b)

In the Office Action, the Examiner maintained the rejection of claims 6-7, 9 and 13-16 under 35 U.S.C. § 102(b) as being anticipated by Paradissis et al. (5,133,974). The Examiner indicated that the Applicant's arguments regarding the differences between a controlled-release coating and a matrix were not persuasive.

In response, although Applicants respectfully disagree with the Examiner’s interpretation that the term “contained in a controlled release matrix” encompasses a drug core with a controlled release coating, the claims have been amended to recite “incorporated into a controlled release coating.” It is respectfully submitted that this claim amendment does not change the scope of the claim.

It is respectfully submitted that Paradissis et al. fails to teach an opioid analgesic “incorporated into a controlled release matrix” as recited in claim 1. It is further submitted that the coated bead formulations (as exemplified by the Paradissis reference) are recognized to one skilled in the art as different than matrix formulations.

Therefore, the Examiner is respectfully requested to remove this rejection.

C. Rejection of Claims 8, 10 and 20-23 under 35 U.S.C. § 103(a)

In the Office Action the Examiner rejected claims 8, 10 and 20-23 under 35 U.S.C. § 103(a) as being unpatentable over Paradissis et al. as applied to claims 6-7, 9 and 11-16. The Examiner asserted that “[i]t would have been obvious to one of ordinary skill in the art to substitute morphine with either oxycodone or hydromorphone . . .” and that “[i]t would have been obvious to one of ordinary skill at the time of the invention to exemplify the formulations of Paradissis et al. as comprising at least 50 mg of drug because of the expectation of achieving dosage amounts that are effective to treat different levels of pain”

This rejection is traversed. It is respectfully submitted that even assuming arguendo that one skilled in the art would be motivated to substitute hydromorphone or oxycodone for morphine in the formulations described in the Paradissis reference as asserted by the Examiner, one skilled in the art would not arrive at the presently claimed formulations for the reasons set forth above with respect to claim 6.

Therefore, the Examiner is respectfully requested to remove the obviousness rejection.


IV. CONCLUSION

In view of the arguments presented, it is respectfully requested that the Examiner's rejections be withdrawn. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application. An early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

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